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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,976	11/21/2003	Xuedong Song	KCX-693 (19341)	1744
22827	7590	11/23/2009		
DORITY & MANNING, P.A. POST OFFICE BOX 1449 GREENVILLE, SC 29602-1449			EXAMINER DIRAMIO, JACQUELINE A	
			ART UNIT 1641	PAPER NUMBER
			MAIL DATE 11/23/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/719,976	<b>Applicant(s)</b> SONG, XUEDONG	
	<b>Examiner</b> JACQUELINE DIRAMIO	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6,9-13 and 39-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,9-13 and 39-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Currently, claims 1 – 6, 9 – 13, and 39 – 45 are pending and under examination.

### ***Withdrawn Rejections***

2. All previous rejections of the claims under 35 U.S.C. 103(a) are withdrawn in view of Applicant's arguments filed July 31, 2009.

### ***Response to Arguments***

3. Applicant's arguments, see pages 6-12, filed July 31, 2009, with respect to the rejection(s) of the claim(s) under 35 U.S.C. 103(a) as being unpatentable over Rylatt et al. (WO 97/09620), as evidenced by Fitzpatrick et al. (US 6,121,008), and further in view of Virtanen (US 2005/021487) and Jou et al. (US 5,670,381) have been fully considered and are persuasive. In particular, Applicant's arguments that the secondary references of Virtanen and Jou et al. fail to render obvious the combination of the charged substances taught by Virtanen and Jou et al., such as the polyelectrolyte substance taught by Jou et al, with the device of Rylatt et al. are found persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made and presented below.

## **NEW GROUNDS OF REJECTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, lines 11-12, recites that the polyelectrolyte has a “net charge opposite to that of the detection probes.” However, after further review, this recitation is considered to lack antecedent basis given that the detection probes are never recited to contain a particular net charge.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1 – 6, 9 – 11, and 39 – 45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24, 25, 30 –

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36, and 41 of copending Application No. 10/132,421 (US 2003/0124739). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the copending application recite a flow-through assay device for detecting an analyte residing in a test sample, the flow-through assay device comprising a porous membrane, said porous membrane being in communication with detection probes conjugated with a specific binding member, said porous membrane defining:

a detection zone within which is immobilized a capture reagent configured to bind with the conjugated detection probes or complexes thereof to generate a detection signal; and

a calibration/compensation zone positioned downstream from said detection zone, wherein a polyelectrolyte is immobilized within said calibration/compensation zone, said polyelectrolyte having a net charge opposite to that of the conjugated detection probes, the polyelectrolyte being configured to bind to said conjugated detection probes to generate a calibration/compensation signal.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Although, it is noted that the claims of the copending application have been allowed.

### ***Conclusion***

6. No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE DIRAMIO whose telephone number is (571)272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline DiRamio/  
Examiner, Art Unit 1641

/GAILENE R. GABEL/  
Primary Examiner, Art Unit 1641

11/19/09